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REMARKS

Claims 10-20 and 38-63 are pending in the instant application.

The specification has been amended to remove embedded hyperlinks. Claim 13 has been amended to recite that the nucleic acid encodes "a protein that competes for binding to CD40 with monoclonal antibody S2C6 as secreted by the hybridoma deposited with the ATCC and assigned accession number PTA-110." Support for this amendment can be found, *inter alia*, page 14, lines 4-6. Claim 16 has been amended to include a definition of high stringency as described in the specification at page 36, line 33 through page 37, line 8. Claims 17 and 18 have been amended to recite that the cell containing a nucleic acid of the invention is an *in vitro* recombinant cell, and claims 19 and 20 have been amended to recite that the recombinant cell containing a nucleic acid of the invention is in culture. Support for this amendment can be found in the specification, for example at page 24, lines 33-36. Claims 17-20 have been amended to recite that the nucleic acid encodes a human constant domain. Support for this amendment can be found in the specification, for example at page 24, lines 28-30 and at page 25, lines 1-6. Unrelated to patentability, claim 38 has been amended to correct an editorial error. Claim 45, which the Examiner alleges to be a substantial duplicate of claim 15, has been canceled without prejudice. Claim 49 has been canceled without prejudice. No new matter has been added.

Following entry of the amendments made herein, claims 10-20, 38-44 and 46-48 and 50-63 will be pending in the instant application

OBJECTION TO THE SPECIFICATION

In paragraph 3 of the Office Action dated November 12, 2003, the Examiner objected to the disclosure because it contains embedded hyperlinks. The specification has been amended to remove all embedded hyperlinks. Accordingly, Applicants request that the objection be withdrawn.

OBJECTION TO THE CLAIMS

In paragraph 4 of the Office Action dated November 12, 2003, the Examiner objected to claim 45 as allegedly being a substantial duplicate of claim 15. In response, Applicants have canceled claim 45, without prejudice, rendering this objection moot.

THE REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

In paragraph 5 of the Office Action dated November 12, 2003, the Examiner rejected claims 16 and 55-58 under 35 U.S.C. § 112, second paragraph as indefinite. The Examiner

believes that the recitation in these claims of the term "highly stringent conditions" renders these claims indefinite because the term is exemplified rather than defined in the specification.

In response, Applicants have amended claim 16 (and claims 55-58 dependent thereon) to include specific conditions of high stringency, as taught in the specification at page 36, line 33 through page 37, line 8.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the rejection of claims 16 and 55-58 under 35 U.S.C. § 112, second paragraph, has been obviated and should be withdrawn.

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF ENABLEMENT

In paragraph 6 of the Office Action dated November 12, 2003, the Examiner rejected claims 12, 14, 17, 19, 43, 44 and 52-58 under 35 U.S.C. §112, first paragraph, for lack of enablement, as a result of an alleged failure to provide sufficient assurance that the conditions of 37 C.F.R. §§ 1.801-1.809 have been met with respect to the hybridoma deposited with the ATCC and assigned accession number PTA-110.

In response to this rejection, Applicants submit herewith a "Statement of Attorneys for Applicants Regarding Permanence And Availability of Deposited Microorganisms," which provides the requisite assurances, accompanied by a copy of the relevant International Form of deposit receipt from the ATCC. Accordingly, the rejection is obviated and should be withdrawn.

In paragraph 7 of the Office Action dated November 12, 2003, the Examiner rejected claim 49 under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner contends that claim 49 is directed to a nucleic acid encoding a human antibody having a particular amino acid sequence, and the specification allegedly does not teach how to screen for a human antibody with a particular amino acid sequence.

Without agreeing with the rejection, and merely to expedite prosecution, Applicants have canceled claim 49, without prejudice, rendering this rejection moot.

In paragraph 9 of the Office Action dated November 12, 2003, the Examiner rejected rejected claims 17-20, 61 and 62 under 35 U.S.C. §112, first paragraph, for lack of

enablement. The Examiner contends that claim the specification is only enabling for recombinant cells *in vitro* or recombinant cells *in vivo* within a transgenic mouse, but is not enabling for a recombinant cell *in vivo* in an animal other than a mouse.

Without agreeing with the rejection, and merely to expedite prosecution, Applicants have amended claims 17 and 18 have been amended to recite that the recombinant cell containing a nucleic acid of the invention is an *in vitro* recombinant cell, and claims 19 and 20 have been amended to recite that the recombinant cell containing a nucleic acid of the invention is in culture, which the Examiner acknowledges to be enabled subject matter. Applicants submit that the foregoing amendments obviate the rejection of claims 17-20, 61 and 62 under 35 U.S.C. §112, first paragraph, for lack of enablement.

In view of the foregoing, Applicants believe this rejection under 35 U.S.C. § 112, first paragraph, is moot and should be withdrawn.

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF WRITTEN DESCRIPTION

In paragraph 8 of the Office Action dated November 12, 2003, the Examiner rejected claims 13, 16, 39, 40, 41, 42, 46-49 and 52-58 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that claims 42, and claims 52-54 dependent thereon, are drawn to molecules "without structural characterization" because the nucleic acids encompassed by these claims encode molecules which do not necessarily comprise the antigen-binding portions of S2C6 or bind to CD40 at the same epitope as S2C6. The Examiner contends that, because the claims are not defined in terms of nucleic acid sequences, but only in terms of function, that is, encoding a protein having a particular activity, that the claims fail to meet the written description requirement of 35 U.S.C. § 112, first paragraph.

The Examiner further contends that claims 13, 16, 39 and 40 and claims 46-49 and 55-58 dependent thereon are drawn to nucleic acids encoding molecules "which vary from the variable chain and CDR structure of the S2C6 antibody which encompass different functional attributes of S2C6" without necessarily binding to the same epitope on CD40 as S2C6.

The Examiner further states that Applicants "must set apart the genus of antibodies claimed from the antibodies of the prior art by means of functional and structural attributes." The Examiner further states Applicants have described only one specie that possesses the

functional attribute ("increas[ing] the binding of CD40 ligand to CD40") that sets apart the claimed genus from the prior art, and that the claims should therefore be restricted to nucleic acids encoding molecules with the same epitope specificity as S2C6.

Without agreeing with the Examiner in any way, and merely to expedite prosecution, the rejected claims have been amended to recite that the claimed nucleic acids encode molecules that compete for binding to CD40 with monoclonal antibody S2C6 as secreted by the hybridoma deposited with the ATCC and assigned accession number PTA-110.

In view of the foregoing amendments and remarks, Applicants submit that the rejection of claims 13, 16, 39, 40, 41, 42, 46-49 and 52-58 under 35 U.S.C. § 112, first paragraph, for lack of written description, has been obviated and should be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 102(b)

Claims 17-20, 61, and 62 are rejected under 35 U.S.C. § 102(b), allegedly as anticipated by Koho. According to the Examiner, claims 17-20, 61 and 62 read on the S2C6 hybridoma taught by Koho. The Examiner alleges that the S2C6 hybridoma is a recombinant cell "because it comprises a myeloma cell fused to the spleen cell" and that the nucleic acids encoding the S2C6 antibody are recombinant because "said nucleic acid sequences are formed by recombination events within the spleen cell." According to the Examiner, such "recombinant" nucleic acids are contemplated by the specification.

In response, without agreeing with the Examiner's contention and merely to expedite prosecution, Applicants have amended claims 17-20, and thus also claims 61 and 62 dependent thereon, to recite that the antibody has a human constant domain. The S2C6-hybridoma does not comprise a recombinant nucleic acid that encodes an anti-CD40 antibody that comprises a human constant domain, nor does Koho suggest such a recombinant nucleic acid, let alone one having the sequences encompassed by claims 17, 18 and 20.

In view of the foregoing amendments and remarks, Applicants submit that the rejection of claims 17-20, 61 and 62 under 35 U.S.C. § 102(b) has been obviated and should be withdrawn.

CONCLUSION

Applicants respectfully request consideration of the foregoing remarks and entry of the foregoing amendments into the file of the above-identified application. Applicants believe that each ground for rejection has been successfully overcome or obviated, and that

all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and allowance of the application are respectfully requested.

Respectfully submitted,

by Adriane M. Antler Reg No 40,203

Date: February 12, 2004

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Enclosures